



December 2016

FDA FACILITIES

Planning Efforts for
White Oak Campus
Should Further
Incorporate Leading
Practices to Address
Ongoing Challenges

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Why GAO Did This Study

In 1990, Congress mandated that FDA consolidate its facilities in the national capital area. Consolidation began in 2003. Currently, about 10,500 FDA staff and contractors work in about 3.8 million square feet at the federally owned White Oak campus, which is managed by GSA. In 2016, FDA proposed locating an additional 5,900 staff at White Oak by 2020. FDA is in the process of updating the master plan for the White Oak campus.

GAO was asked to examine the status of the White Oak campus. This report examines (1) the benefits and challenges FDA experienced at the White Oak campus; and (2) FDA's plans for the future of the White Oak campus. GAO reviewed planning documents, cost data, Interagency Security Committee standards, and FDA's White Oak facility risk assessment; interviewed FDA and GSA officials; conducted semi-structured group interviews with randomly selected White Oak staff; and assessed FDA's planning in light of leading practices for strategic facilities planning and consolidation.

What GAO Recommends

GAO recommends that FDA, in consultation with GSA, (1) implement a vehicle separation system as called for in the 2014 risk assessment; (2) establish strategic linkage between its strategic priorities and its facilities plans; and (3) develop a strategy for collecting and analyzing needed data to inform proposed facilities planning efforts.

HHS and GSA concurred with GAO's findings, and HHS concurred with GAO's recommendations.

View [GAO-17-87](#). For more information, contact Elizabeth H. Curda at (202) 512-7114 or curdae@gao.gov or David J. Wise at (202) 512-2834 or WiseD@gao.gov.

What GAO Found

Officials from the Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS) described various benefits and challenges related to the consolidation of about 10,500 FDA staff and contractors at a campus in White Oak, Maryland. As of 2016, the campus was partially complete, with 9 of the 10 planned office buildings constructed and 27 percent more staff than the 8,297 staff planned for in the completed buildings. Benefits of the consolidation cited by FDA officials included increased collaboration and improvements in efficiency from factors such as co-located staff and shared labs. FDA has also faced various challenges related to managing staff growth at White Oak within the existing campus infrastructure, such as providing sufficient office space and parking for staff. FDA's White Oak campus was designated as a high-risk facility in a 2014 risk assessment, according to Interagency Security Committee standards. However, in part, due to concerns about managing traffic and parking, FDA has faced challenges implementing the required vehicle separation system and controlling visitor access to parking, which was identified in the 2014 risk assessment. In the absence of these recommended security features, FDA is not in compliance with guidance and may put the campus at risk. According to FDA officials, FDA plans to institute a vehicle separation system, controlling visitor access to parking, in the near future. However, to-date, FDA has not documented plans for its vehicle separation system.

FDA has taken steps to plan for the future of the White Oak campus, but its planning efforts lack some elements of leading practices for facilities planning. FDA published a 5-year facilities plan in 2015—its existing plan—and, in consultation with the General Services Administration (GSA), recently developed scopes of work for proposed planning efforts related to White Oak. In these existing and proposed plans, FDA did not create or call for explicit linkages between its facilities' needs and the agency's broader strategic priorities, as recommended by leading practices, and instead relied on general linkages to agency mission. For example, in its existing plan, FDA did not describe how proposed solutions to space needs would help accomplish FDA's strategic goals and objectives, such as enhancing productivity and capabilities. According to FDA officials, strategic linkages were implicit in the agency's facilities planning process. Proposed planning efforts incorporate some leading practices, such as calling for a facility condition assessment, which may help identify gaps between current conditions and needs, and an evaluation of alternatives. On the other hand, inconsistent with leading practices, FDA lacks key information needed to inform these planning efforts, because it has limited data on daily operations—such as daily campus population and parking usage—or on benefits and challenges of the consolidation. FDA's proposed planning efforts call for improved data, but lack a detailed strategy for collecting and analyzing key information in these areas. Without strategic linkages between strategic priorities and plans and more comprehensive data, there is limited assurance that recommendations developed in proposed planning efforts for the future of the White Oak campus will represent the full scope of facility needs, and successfully identify the strengths and weaknesses of different development alternatives in order to guide decisions, and reflect agency priorities.

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Abbreviations

FDA	Food and Drug Administration
GSA	General Services Administration
HHS	Department of Health and Human Services
HVAC	heating, ventilation, and air conditioning
IFMA	International Facility Management Association
ISC	Interagency Security Committee
OMB	Office of Management and Budget

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December 7, 2016

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate

The Food and Drug Administration's (FDA) headquarters campus in White Oak, Montgomery County, Maryland, has been in development for over 25 years.¹ In 1989, we found that FDA's headquarters offices and laboratories were dispersed across seven sites throughout the national capital area, and we reported serious problems with these facilities, including crowded spaces, leaking pipes, and damaged ceilings.² At that time, FDA and the General Services Administration (GSA) advocated that the most efficient way for FDA to carry out its mission would be to consolidate its activities at a single campus-like location. In 1990, Congress mandated that the FDA consolidate its facilities in the national capital area.³ Since that time, FDA and GSA have jointly developed FDA's headquarters campus on federally owned property at White Oak in Maryland. The first group of staff arrived in 2003. As of 2016, about 10,500 FDA staff and contractors were assigned to 3.8 million gross square feet of laboratory and office space at the White Oak campus, and FDA and GSA had jointly funded almost \$1.5 billion for this consolidation effort. In 2016, FDA stated that, to accommodate existing staff waiting to move to White Oak and expected staff increases, it would like to expand the consolidation project to locate an additional 5,900 staff at White Oak

¹FDA is part of the Department of Health and Human Services (HHS).

²See GAO, *FDA Resources: Comprehensive Assessment of Staffing, Facilities, and Equipment Needed*, [GAO/HRD-89-142](#) (Washington, D.C.: Sept. 15, 1989). The national capital area refers to the Washington, D.C., metropolitan area.

³Food and Drug Administration Revitalization Act, Pub. L. No. 101-635, 104 Stat. 4583 (1990).

by 2020. According to an explanatory statement accompanying the Consolidated Appropriations Act of 2016, FDA's appropriation included \$5 million to complete a feasibility study to update and issue a revised master plan for the White Oak campus.⁴

FDA oversees, among other things, the safety of most of America's food supply; the safety and effectiveness of drugs, biologics, and medical devices; the purity of the blood supply; and the regulation of tobacco products.⁵ Since the conception of the White Oak consolidation project, FDA has taken on new responsibilities that include establishing a new center related to the oversight of tobacco products and strengthening of the program for the development of bioterrorism counter measures.⁶ According to FDA, its centers have also grown in size during this time, primarily related to authorized user fee programs.⁷ FDA's overall staffing levels increased 5 percent to 10 percent per year over the last decade.

Given the changes that have occurred in FDA since the consolidation was mandated, including continued staff increases, you requested that we provide information on the status of FDA's consolidation at White Oak, including plans for the future. In this report, we examine (1) benefits and challenges related to FDA's consolidation at the White Oak campus; and (2) the steps FDA has taken to plan for the future of the White Oak consolidation project.

⁴The Explanatory Statement accompanying Pub. L. No. 114-113 was published in the December 17, 2015, daily edition of the Congressional Record.

⁵Biologic products such as vaccines and blood products are derived from living sources such as humans, animals and microorganisms.

⁶The Family Smoking Prevention and Tobacco Control Act of 2009 gave the FDA new authority to regulate tobacco products to reduce the harmful effects of tobacco. Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776 (2009). FDA also has responsibilities to ensure that medical countermeasures—including drugs, vaccines, and diagnostic tests to counter chemical, biological, radiological, nuclear, and emerging infectious disease threats—are safe, effective, and secure.

⁷A user fee is a charge assessed to beneficiaries for goods or services provided by the federal government. FDA is authorized to collect user fees for reviewing certain applications and licenses and use the proceeds to cover the costs associated with these applications, such as lease payments and furniture, fixtures and equipment, as approved in annual appropriations, 21 U.S.C § 379h; 21 U.S.C § 379j; 21 U.S.C § 379j-12; 21 U.S.C § 379j-21; 21 U.S.C § 379j-31; 21 U.S.C § 379j-42; 21 U.S.C § 379j-52. FDA also collects tobacco user fees to fund all activities of the Center for Tobacco Products. Tobacco user fees are assessed based on industry market share.

To examine the benefits and challenges related to FDA's consolidation at the White Oak campus, we reviewed the current status of the consolidation using FDA and GSA planning documents, such as the 2006 and 2009 master plans related to the White Oak campus, White Oak project costs and schedules, and FDA leases.⁸ We also reviewed FDA's transportation and parking plan and space management plans. We reviewed FDA's 2014 risk and security assessment for the White Oak campus, which was performed to the standards of the Interagency Security Committee (ISC), and we discussed with FDA officials any actions FDA had taken to comply with requirements related to the results of this security assessment.⁹

We reviewed FDA documents to assess FDA's expanded mission and staffing levels, as well as how FDA incorporated the Office of Management and Budget's (OMB) space efficiency initiatives.¹⁰ We interviewed GSA and FDA officials (including FDA officials responsible for facilities management, strategic planning, security, transportation and

⁸2006 Master Plan Update / FDA Consolidation White Oak Maryland, Kling in Association with RTKL, June 2006. 2009 Master Plan Update Volume I FDA Consolidation White Oak, Maryland, Kling Stubbins in Association with RTKL, July 2009.

GSA has custody and control of the White Oak campus and FDA leases space at the White Oak campus and in other facilities in the national capital area through GSA. This leasing information is stored in GSA's Real Estate Across the United States database. We obtained information about all the FDA leases in the national capital area.

⁹Pursuant to the authority of the ISC contained in Executive Order (E.O.) 12977, October 19, 1995, "Interagency Security Committee", as amended by E.O. 13286, March 5, 2003, The Risk Management Process for Federal Facilities: An Interagency Security Committee Standard is applicable to all buildings and facilities in the United States occupied by federal employees for nonmilitary activities. The resulting Facility Security Level determination ranges from a Level I (lowest risk) to Level V (highest risk). Risk assessments are to be conducted at least once every five years for Level I and II facilities and at least once every three years for Level III, Level IV, and Level V facilities. The Facility Security Levels are to be reviewed and adjusted, if necessary, as part of each initial and recurring risk assessment. The responsibility for making the final Facility Security Level determination rests with the tenant(s) who must devise a risk management strategy and, if possible, fund the appropriate security countermeasures to mitigate the risk. Department of Homeland Security, National Protection and Programs Directorate, Federal Protective Service, Vulnerability Survey Report, FDA White Oak Campus, January 2014.

¹⁰Executive Office of the President, Office of Management and Budget, *Promoting Efficient Spending to Support Agency Operations*, OMB Memorandum No. 12-12 (Washington, D.C.: May 11, 2012); OMB Memorandum No. 2013-02, Implementation of OMB Memorandum M-12-12 Section 3: *Freeze the Footprint* (Washington, D.C.: March 14, 2013); and OMB Memorandum No. 2015-01, Implementation of OMB Memorandum M-12-12 Section 3: *Reduce the Footprint* (Washington, D.C.: March 25, 2015).

parking, and laboratories, and officials of four FDA centers at the White Oak campus, as well as a labor relations official representing FDA staff at White Oak) to determine their views on the benefits and challenges experienced by FDA by consolidating into a campus-like setting; and to determine the availability of information or performance metrics for measuring the impact of the consolidation.¹¹

We reviewed FDA data related to the potential benefits and challenges of the consolidation, such as the size of FDA's automobile fleet; rental payments made by FDA to hotels and other venues for conferences and training; the number of parking spaces; and the daily number of staff and visitors on campus. Through interviews with FDA and GSA officials and spot-checking for missing data, outliers, and errors, we determined that these data were sufficiently reliable for our purposes.

To further understand the perspective of FDA staff regarding the benefits and challenges related to the consolidation, we conducted 10 semi-structured group interviews with randomly selected management and non-management staff at four FDA centers and one FDA office located at the White Oak campus: the Center for Biological Evaluation and Review, the Center for Drug Evaluation and Review, the Center for Devices and Radiological Health, the Center for Tobacco Products, and the Office of the Commissioner.¹² The information we obtained from these interviews is

¹¹We interviewed an official of the union representing FDA employees to gather information about how FDA employees were affected by the consolidation and to obtain the perspective of employees about the challenges being faced by FDA employees as a result of the consolidation.

To assess the impact of the consolidation, we requested data from FDA to demonstrate the effects of the consolidation on FDA's operation. For example, we obtained information on the change in the size of the vehicle fleet managed by FDA; the amount of rental payment made to hotels and other facilities for hosting conferences and training; and the number of conferences held on the White Oak campus.

¹²To select FDA staff for our semi structured group interviews, we obtained data listing all FDA staff at the White Oak campus that included information such as names, title, and grade. We sorted the list into managers and non-managers using each individual's grade level. For each FDA center, as well as other FDA offices assigned to the White Oak campus, such as the Office of the Commissioner, we randomly selected and invited 8 managers and 8 non-managers to the small group sessions. The semi structured interview sessions were attended by 67 total FDA staff, covered seven broad topic areas related to the consolidation, and lasted approximately 2 hours each. We selected the Office of the Commissioner because it is responsible for agency-wide program direction and management.

not generalizable to FDA staff as a whole, but serves to provide illustrative examples of benefits and challenges identified by certain staff.

To examine the steps FDA has taken to plan for the future of the White Oak consolidation project, we reviewed FDA planning documents, such as its fiscal year 2017 facilities plan and associated center-level information packages.¹³ We also reviewed FDA's and GSA's proposed scopes of work for a master housing strategy and migration plan and Federal Research Center master plan update. We identified leading practices for capital planning and strategic facilities planning from GAO's Executive Guide, OMB's Capital Programming Guide, and our prior work and assessed the extent to which FDA's planning efforts incorporate these leading practices.¹⁴ We also interviewed FDA and GSA officials.

We conducted this performance audit from January 2016 to December 2016 in accordance with generally accepted government auditing standards. These standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

As required by the FDA Revitalization Act of 1990, FDA has been consolidating its dispersed national capital area facilities from outdated leased spaces onto a federal campus that includes new facilities and laboratories.¹⁵ According to language in the conference report accompanying the act, some of the consolidation objectives are to

¹³In addition, we reviewed the FDA Five-Year Infrastructure Strategic Plan (Dec. 15, 2015) and the FDA Laboratory Revitalization Plan (Oct. 1, 2014) activity description.

¹⁴See GAO, *Executive Guide: Leading Practices in Capital Decision-Making*, [GAO/AIMD-99-32](#) (Washington, D.C.: Dec. 1, 1998). In assisting with the development of OMB's Capital Programming Guide, we identified leading practices in capital decision making used by state and local governments and private sector organizations. OMB, *Capital Programming Guide*, Supplement to Office of Management and Budget Circular A-11: Planning, Budgeting, and Acquisition of Capital Assets (July 2016). See also GAO, *VA Real Property: Realignment Progressing, but Greater Transparency about Future Priorities Is Needed*, [GAO-11-197](#) (Washington, D.C.: Jan. 31, 2011); and *Afghanistan: Embassy Construction Cost and Schedule Have Increased, and Further Facilities Planning Is Needed*, [GAO-15-410](#). (Washington, D.C.: May 19, 2015).

¹⁵Food and Drug Administration Revitalization Act, Pub. L. No. 101-635, 104 Stat. 4583 (1990).

improve the working environment for FDA headquarters personnel; streamline headquarters activities and operations, and improve efficiency; improve collaboration among FDA scientists and officials; create state-of-the-art laboratory facilities; and establish FDA as a major research and biomedical institution.¹⁶ In 1995, in Conference Report language, Congress requested that GSA examine the potential to develop the consolidated campus on 130 acres of a federally owned site in White Oak, Maryland, that formerly housed a United States Department of the Navy facility.¹⁷ After the site was transferred to GSA, it became known as the Federal Research Center.¹⁸ In 1997, GSA decided to consolidate FDA's headquarters at the White Oak site, and FDA and GSA created a master plan to guide the planning and construction of the White Oak campus. This master plan was updated in 2002, 2006, and most recently in July 2009.

As of the 2009 master plan—hereafter referred to as the master plan—FDA expected to house six FDA centers or offices at White Oak, including the Office of the Commissioner, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Office of Regulatory Affairs, and the Center for Veterinary Medicine.¹⁹ However, FDA subsequently decided to locate the Center for Tobacco Products—established in response to the 2009 Family Smoking Prevention and Tobacco Control Act—on the White Oak campus, and as a result did not move the Center for Veterinary Medicine to White Oak as planned. In addition, the Office of Regulatory Affairs was only partially moved to White Oak, with 88 percent of its headquarters' staff still located in other leased facilities as of June 2016. The centers

¹⁶S. Rpt. No. 101-242, at 9, 11-12 (1990) (Conf. Rep.).

¹⁷H.R. Rep. No. 104-291, at 46 (1995) (Conf. Rep.).

¹⁸The site encompasses 710 acres and lies within Montgomery County and Prince George's County of Maryland. The 130 acre FDA campus is located at the west end of the property, where the original Naval Surface Warfare Center was located. According to GSA officials, due to wetlands, there only three locations on the site, totaling approximately 110 acres that can be further developed.

¹⁹The FDA's organization consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations. Within these directorates are offices and centers. The Center for Veterinary Medicine was originally planned to consolidate in Prince George's County, Maryland. The National Center for Toxicological Research is headquartered in Jefferson, Arkansas, and is not included in consolidation efforts.

related to foods, specifically the Center for Food Safety and Applied Nutrition, were separately consolidated in College Park, Maryland, in 2001.²⁰

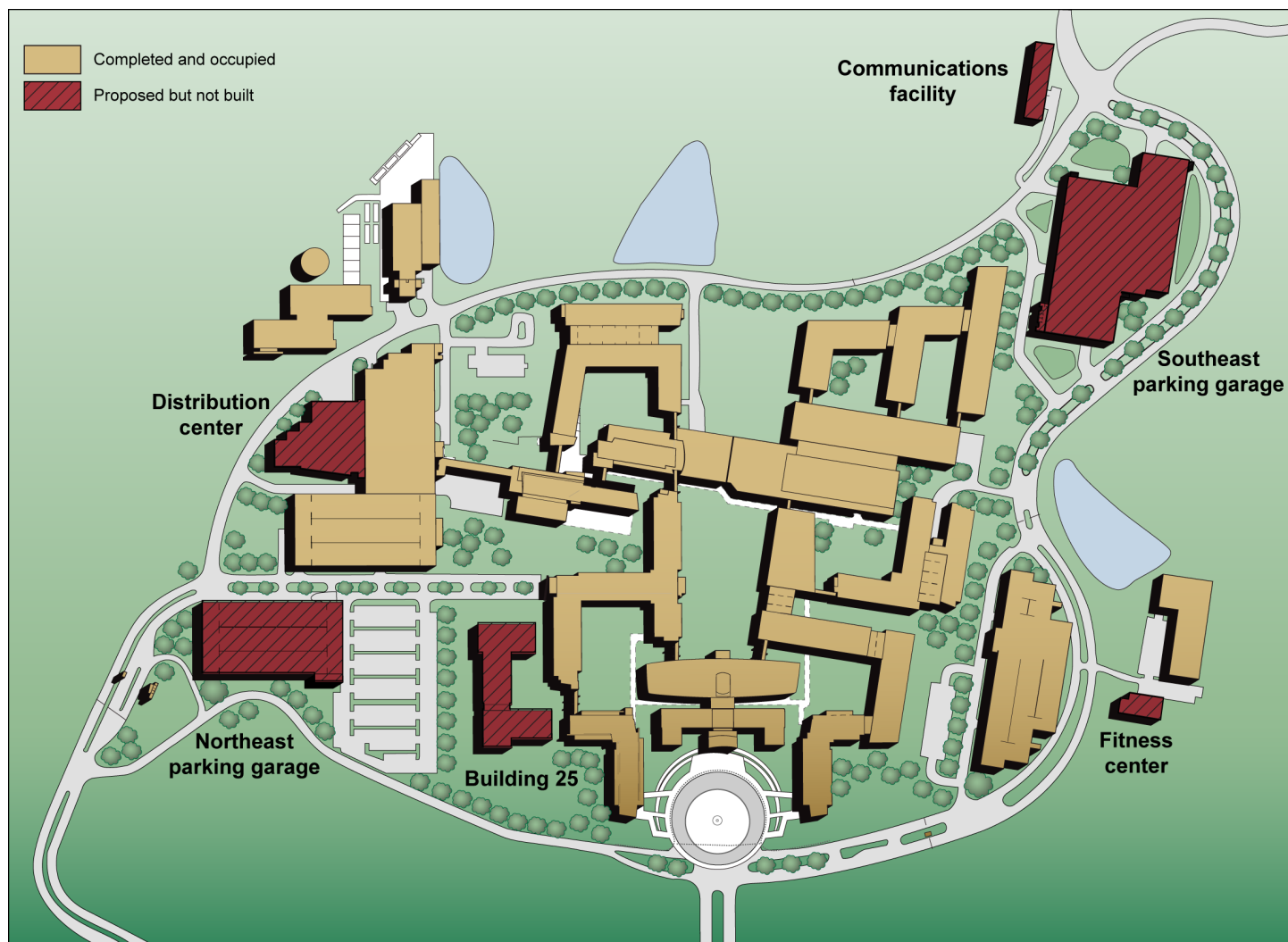
Phased construction at the White Oak campus started in 2001 and continued through 2014, when the last FDA centers moved onsite.²¹ However, the current campus does not include key facilities that were identified in the master plan and has more FDA staff and contractors assigned to the campus than estimated in the plan. The master plan identified that 10 office buildings, 3 labs, 5 additional support facilities, and 5 parking garages would be built on the FDA White Oak campus. According to FDA and GSA officials, GSA lacked sufficient funding to complete the White Oak campus facilities as proposed in the master plan. These officials stated that FDA chose to prioritize GSA construction of laboratories, and defer several other structures, including an office building, 2 parking garages, a distribution center for deliveries, a global communications center, and a fitness center. As a result of deferring the 2 parking garages, almost 51 percent of the planned garage parking spaces (3,297 of 6,515) have not been built.²² (See fig. 1.)

²⁰In 2001, FDA consolidated the Center for Food Safety and Applied Nutrition to the Harvey W. Wiley Federal Building in College Park, Maryland.

²¹In 2003, FDA planned to consolidate the Center for Veterinary Medicine to the White Oak campus. Since then, FDA decided to consolidate the Center for Tobacco Products to the White Oak campus in lieu of Center for Veterinary Medicine.

²²The master plan identified the need for 6,926 parking spaces (in parking garages and surface lots) as authorized by the National Capital Planning Commission based upon a ratio of 2:3 for FDA staff and contractors, and 1,000 spaces for visitors. The National Capital Planning Commission is an independent executive branch agency that operates under laws and authorities that it also implements, including: The National Capital Planning Act, National Historic Preservation Act and National Environmental Policy Act.

Figure 1: FDA's White Oak Campus as Planned in 2009, with Unconstructed Facilities as of 2016 Highlighted



Source: GAO analysis of Food and Drug Administration (FDA) information. | GAO-17-87

The master plan for the White Oak campus estimated the space needs for 8,889 FDA staff and contractors and over 1,000 visitors.²³ Looking only at the number of FDA staff and contractors assigned to completed office buildings (i.e., not including those planned to be assigned to the one office building that was not constructed), as of April 2016, FDA

²³2009 Master Plan Update Volume I, *FDA Consolidation White Oak Maryland*, Kling Stubbins in Association with RTKL, July 2009.

officials had assigned almost 27 percent more FDA staff and contractors in the completed buildings than envisioned (10,511 versus 8,297). (See table 1.)

Table 1: Food and Drug Administration (FDA) Staff and Contractors Planned for and Assigned to the White Oak Campus, by Center or Office, 2009 and 2016

Center or Office	FDA planned for per Master Plan	FDA personnel assigned April 2016 per FDA
Center for Biological Evaluation and Research	1,343	1,325
Center for Devices and Radiological Health	1,406	1,823
Center for Drug Evaluation and Research	3,122	4,872
Center for Veterinary Medicine	519	1
Office of Regulatory Affairs	428	74
Office of the Commissioner	1,781	416
Center for Tobacco Products	0	674
Office of Operations	0	888
Other miscellaneous offices	290	438
Total planned for and actual personnel on White Oak Campus	8,889	10,511
Total planned for and actual personnel in completed buildings ^a	8,297	10,511
Percent excess personnel assigned versus planned for in completed buildings		27%

Source: GAO analysis of master plan and FDA data. | GAO-17-87

Notes: FDA officials estimate a varying daily visitor population of 680 to 1,800 not included in the table.

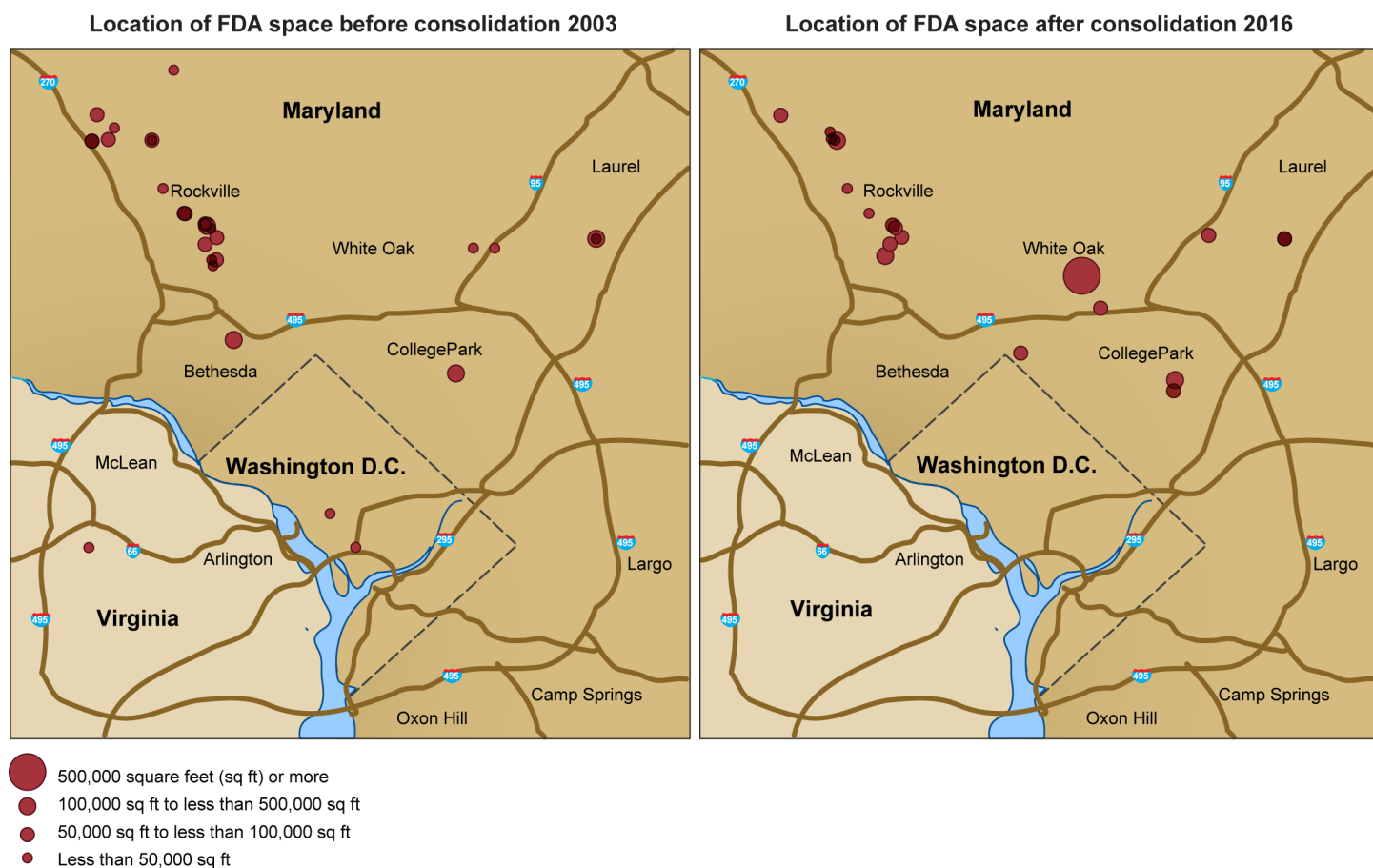
^aPer the master plan, the combined planned personnel population of uncompleted buildings is 592; therefore, the planned personnel population for the completed buildings is 8,297 (8,889–592).

Although FDA's facilities are more consolidated than prior to the development of the White Oak campus, FDA still has staff and contractors located in multiple facilities around the national capital region. Since 2003, when staff and contractors began moving to the White Oak

campus, FDA terminated 19 leases consisting of almost 1.2 million square feet. However, in addition to the White Oak campus, FDA currently has leases through GSA at 19 locations for almost 1.6 million square feet in the national capital region, including space for staff and contractors in centers that were never envisioned to be consolidated at White Oak, such as the Center for Food Safety and Applied Nutrition, as well as space for staff in centers that have been partially consolidated at White Oak or that were initially envisioned to be moved to White Oak, but were not.²⁴ (See fig. 2.)

²⁴As of 2016, FDA had 290 leases agency wide through GSA for almost 6.7 million square feet. FDA's reliance on leasing is not unique to the agency, as our prior work has found that the federal government continues to rely heavily on leasing properties where it would be more cost efficient for the federal government to own. See GAO, *High Risk Series: An Update*, [GAO-15-290](#) (Washington, D.C.: Feb. 11, 2015). We also recommended that GSA should enhance the transparency of decision making for high-value leases (leases requiring a prospectus) by, among other things, prioritizing potential ownership solutions for current high-value leases to help create a long-term strategy for targeted ownership investments. GSA concurred with our recommendations, but has not fully implemented them. See GAO, *Federal Real Property: Greater Transparency and Strategic Focus Needed for High-Value GSA Leases*, [GAO-13-744](#) (Washington, D.C.: Sept. 19, 2013). Prior to receiving an appropriation by Congress to lease space above an average annual cost of \$1.5 million, GSA must transmit a prospectus of the proposed project to Congress. 40 U.S.C. § 3307(b). GSA may annually adjust this dollar threshold to reflect increases or decreases in construction costs as determined by the composite index of construction costs of the Department of Commerce. 40 U.S.C. § 3307(h). According to GSA's budget justification for fiscal year 2016, the dollar threshold for requiring a prospectus of the proposed project is \$2.85 million or more.

Figure 2: Locations Occupied by the Food and Drug Administration (FDA) in the National Capital Area, 2003 and 2016



Sources: GAO analysis of Food and Drug Administration (FDA) information; MapResource and MapInfo (map). | GAO-17-87

OMB issued three government-wide space-related initiatives during FDA and GSA's planning and construction of the White Oak campus with the goal of saving money through increasing the efficient use of space. In its fiscal year 2017 Strategic Facilities Plan, FDA noted that these policies are in direct conflict with FDA's continuing growth and increasing space needs.

- In 2012, OMB introduced the "Freeze the Footprint" policy, instructing executive departments and agencies, among other things, to not

increase the total square footage of their domestic office and warehouse inventory compared to their fiscal year 2012 baseline.²⁵

- In 2015, OMB issued its “National Strategy for the Efficient Use of Real Property for 2015-2020” and its “Reduce the Footprint” policy. The Reduce the Footprint policy requires certain executive departments and agencies (including FDA) to (1) set annual square foot reduction targets for domestic federal buildings, and (2) adopt space design standards to optimize federal domestic office space usage.²⁶

In addition, in December 2010, Congress enacted the Telework Enhancement Act of 2010, which required that the Office of Personnel Management assist each executive agency in establishing and meeting telework participation goals, and required each executive agency’s Chief Human Capital Officer to submit an annual report on the agency’s efforts to promote telework to the Chair and Vice Chair of the Chief Human Capital Officers Council. We recently reported that while several agencies identified various benefits associated with telework, such as improved work/life balance and reduced real estate use, they generally lacked supporting data on these benefits or associated costs.²⁷

User fees have been a key driver of FDA staffing growth in recent years, including for some of the centers housed at the White Oak campus. For example with the Prescription Drug User Fee Act program, which allows FDA to hire more review and support staff to speed new drug reviews, the number of such staff working in the new drug review process increased almost 20 percent (from 2,416 to 2,888) from fiscal year 2010 to fiscal year 2015.²⁸ Certain user fees, such as those for medical devices, are available to defray increases in the costs of the resources allocated for

²⁵Executive Office of the President, Office of Management and Budget Memorandum No. 12-12, *Promoting Efficient Spending to Support Agency Operations* (Washington D.C.: May 11, 2012).

²⁶Executive Office of the President, Office of Management and Budget Memorandum No. 2013-02, Implementation of OMB Memorandum M-12-12 Section 3: *Reduce the Footprint* (Washington, D.C.: March 14, 2013); and OMB Memorandum No. 2015-01, Implementation of Memorandum M-12-12 Section 3: *Reduce the Footprint* (Washington, D.C.: March 25, 2015).

²⁷See GAO, *Federal Telework: Better Guidance Could Help Agencies Calculate Benefits and Costs*, [GAO-16-551](#) (Washington, D.C.: July 15, 2016).

²⁸FDA’s prescription drug user fees pay the costs of the process for the review of human drug applications (21 U.S.C. § 379h).

the application review process, such as leasing costs. However, FDA does not have statutory authority to use or transfer its annually appropriated funds or proceeds from user fees to build facilities on the GSA-controlled White Oak campus.

As of June 2016, GSA had spent almost \$1 billion to construct the White Oak campus. (See app. I.) In addition, FDA had spent almost \$448 million in annually appropriated funds and user fees for upgrades to GSA standard construction, furniture, fixtures, and equipment.²⁹ (See app. II.) In its fiscal year 2016 budget justification to Congress, FDA estimated the cost to complete the White Oak campus as envisioned in the master plan to be \$201 million for GSA construction, and \$85 million for FDA upgrades and furniture, fixtures, and equipment. Additionally, in order to help FDA plan for accommodating existing and future FDA staff, and complete the consolidation of the White Oak campus, according to the explanatory statement to the Consolidated Appropriations Act of 2016, FDA's appropriation included \$5 million to update and issue a revised master plan.³⁰

²⁹A user fee is a charge assessed to beneficiaries for goods or services provided by the federal government. FDA is authorized to collect user fees for reviewing certain applications and licenses and use the proceeds to cover the costs associated with these applications, such as lease payments and furniture, fixtures and equipment, as approved in annual appropriations 21 U.S.C § 379h; 21 U.S.C § 379j; 21 U.S.C § 379j-12; 21 U.S.C § 379j-21; 21 U.S.C § 379j-31; 21 U.S.C § 379j-42; 21 U.S.C § 379j-52. FDA also collects tobacco user fees to fund all activities of the Center for Tobacco Products. Tobacco user fees are assessed based on industry market share. GSA allows federal tenants to amortize some above standard construction costs in lease payments (41 C.F.R. § 102-85.15). Above GSA standard construction are items specifically designed to make a GSA-owned building or space meet the needs of a specific tenant—in this case, FDA. These above standard items may include laboratory countertops and upgraded ventilation systems for high-occupancy space.

³⁰The Explanatory Statement accompanying Pub. L. No. 114-113 was published in the December 17, 2015, daily addition of the Congressional Record.

FDA Experienced Various Benefits and Challenges Related to its Consolidation, Including Challenges Related to Mitigating Identified Security Risks

FDA officials and staff from our small group sessions reported improved collaboration, greater efficiency, and improved laboratory facilities resulting from the consolidation at the White Oak campus. These officials and staff also reported that FDA faces challenges with the consolidation related to partially complete construction and managing the growth in FDA's staffing levels. In particular, according to officials, FDA had not mitigated identified security risks as required due in part to logistical concerns about traffic and parking issues.

FDA Officials and Staff Described Benefits from the White Oak Consolidation Related to Improved Collaboration, Efficiency, and Laboratory Facilities

According to FDA officials and FDA staff that participated in our small group sessions, the consolidation at the White Oak campus has resulted in improved collaboration among FDA offices and centers, greater operational efficiencies, and improved laboratories and laboratory support facilities.³¹

Collaboration. FDA officials and FDA staff that participated in our small group sessions noted that the consolidation at White Oak provided opportunities for formal and informal intra- and inter-center collaboration that would have been difficult when FDA's offices and centers were dispersed across the national capital area.³² For example, FDA officials reported greater intra-center collaboration in the areas of device/drug/biologics development, cancer regulation and research, and intra-agency activities. Officials told us that prior to the consolidation, the travel times between FDA offices and centers were an impediment to greater interaction between FDA staff working for different offices and centers. FDA staff that attended our small group sessions reported that following the consolidation at White Oak, there have been greater opportunities for informal communication, such as face-to-face brainstorming and troubleshooting, and that this collaboration has improved their ability to effectively perform their responsibilities in line with FDA's mission.

³¹FDA staff refers to individuals who attended our semi structured small groups interviews, and FDA officials refers to individuals interviewed at other times in their official capacity at FDA.

³²FDA reports that about 10,500 employees and contractors are now assigned to the White Oak campus; in 1989, by comparison, headquarters employees were scattered among 23 facilities at seven sites in the Washington, D.C., metro area.

Operational efficiencies. FDA officials and FDA staff that participated in our small group sessions cited increased operational efficiencies at FDA after the White Oak consolidation. They reported that having a centralized headquarters has allowed FDA to streamline its operations by eliminating duplicative resources and other costs associated with managing multiple sites. For example, officials stated that consolidation has allowed FDA's Office of the Chief Scientist to develop and implement a formal program of sharing costly, new scientific equipment that can be used by multiple users across the White Oak campus. Moreover, FDA officials told us that fewer vehicles are now needed because the offices and centers are less geographically dispersed across the national capital area. Following the consolidation, FDA's offices and centers have been able to share vehicles since the offices are co-located. Based on data provided by FDA officials, due to the consolidation, FDA was able to reduce its automobile fleet in the national capital area by 32 percent from 2009 to 2016—from 157 to 107 vehicles. During that time, according to FDA officials, staff in the national capital area grew 5 to 10 percent annually. Moreover, according to FDA officials, the centralized conferencing and meeting spaces at White Oak—which can be configured in different ways and have a capacity of 600 people—have proved useful as a shared resource for the centers and office. FDA officials and staff reported that the centralized conference and other meeting spaces at White Oak, especially the main auditorium, are heavily used, demonstrating their benefit to serving mission-related needs at FDA, such as required public conferences, workshops, and advisory committee meetings at which FDA receives feedback from the public and interest groups on its regulatory work. Officials and staff told us that in some cases, reservations for the centralized conferencing facilities must be made many months in advance to secure the venue. (See fig. 3.)

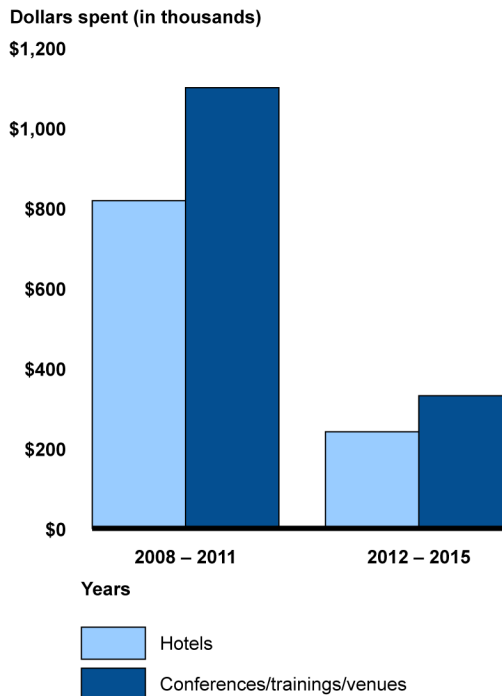
Figure 3: The Food and Drug Administration's (FDA) Central Conferencing



Source: GAO. | GAO-17-87

Furthermore, FDA officials stated that having on-site public conference rooms has allowed FDA to save time and money related to holding meetings at external venues, such as area hotels. According to data provided by FDA, since around the time the White Oak campus conference centers became operational, FDA has spent less on rental payments to external venues for conferences, and training, than it did during the early years of the consolidation. (See fig. 4.)

Figure 4: FDA-Reported Spending for Rental of External Venues for Conferences, Training, and Education, Fiscal Years 2008-2011 and 2012-2015



Source: GAO analysis of Food and Drug Administration (FDA) information. | GAO-17-87

Improved laboratories and support facilities. FDA's laboratory directors and other officials we interviewed reported that FDA has benefitted from the new laboratory research facilities at the White Oak campus. These officials noted that the facilities are not only more modern than the laboratory facilities FDA occupied prior to the consolidation, but were designed in some cases with input from FDA's scientists to ensure they meet both the current and future specialized needs of centers with special missions and functions. According to officials, investing in federally owned laboratories allows the government to make ongoing investments to maintain these facilities over a long period of time compared to a laboratory located in a typical commercially leased space. In particular, according to several FDA officials, new laboratory facilities at the White Oak campus, such as the 3-D printing lab and a mass spectrometer, are valuable resources that can be shared across the agency's centers. Some center officials also reported that staff as a whole enjoy and appreciate having support facilities and services available at the new

campus, such as the fitness facility and child care facilities.³³ FDA staff reported that the new support facilities and services on the White Oak campus have also made it easier to recruit and retain staff.

FDA Officials Reported That White Oak Faces Various Challenges Related to Campus Security, Managing Staff Growth, and Infrastructure, and Has Not Implemented Required Security Measures

According to FDA officials and staff from our small group sessions, several factors—such as the partial completion of the facilities included in the 2009 master plan, additional staff allocated to the White Oak campus, and post-construction government directives mandating greater space efficiency—have led to challenges with the day-to-day operations of the White Oak campus.

Security measures. FDA officials reported the agency has faced challenges implementing the required vehicle security measures related to controlling vehicle access to and parking on the campus identified in a 2014 report assessing risk at the White Oak campus.³⁴ FDA's White Oak campus is subject to a periodic security review using federal interagency security standards.

The 2014 report, the most recent issued, designated the White Oak campus as a high-risk facility.³⁵ According to the ISC guidelines, a high-risk designation means that the White Oak campus must meet certain

³³The fitness center proposed in the 2009 master plan has not been built; however, FDA carved space out of an existing building to add a fitness facility.

³⁴Department of Homeland Security, National Protection and Programs Directorate, Federal Protective Service, Vulnerability Survey Report, FDA White Oak Campus, January 2014.

³⁵To help federal agencies protect and assess risks to their facilities, ISC developed a physical security standard, The Risk Management Process for Federal Facilities: An Interagency Security Committee Standard. The standard is applicable to all buildings and facilities in the United States occupied by federal employees for nonmilitary activities, including the White Oak campus. The standards call for an assessment of the risk to a facility and recommendation of specific security measures commensurate with the level of risk. Subsequent risk management decisions are to be based on the application of risk assessment, risk mitigation, and—when necessary—risk acceptance: the explicit or implicit decision not to implement the recommended security measure, because the tenant agency deemed the risk to be acceptable. The security review is typically performed by the Department of Homeland Security's Federal Protective Service and the security standards, among other things, define the criteria used for the review, as well as physical security countermeasures to be applied. The resulting Facility Security Level determination ranges from a Level I (lowest risk) to Level V (highest risk). In the January 2014 assessment, the White Oak Campus received a Level IV determination.

security criteria, such as controlled vehicle access and parking.³⁶

However, in part, due to traffic and parking concerns and a desire not to slow the flow of vehicles into parking garages, FDA has not implemented vehicular access controls, such as perimeter vehicular barriers, card access drive-on gates, and forced separation of visitor and employee parking.³⁷

In addition, ISC guidance requires agency officials to document the agency's risk management decisions based on the risk assessment. However, we found no evidence that FDA officials documented FDA's risk management decisions, including its decision not to move forward on vehicular access controls. Furthermore, officials said that certain existing features had been suspended, because of technical and logistical issues, and FDA was working to re-implement them by the end of 2016. Specifically, FDA officials said the vehicle separation system of barriers and gates—controlling visitor access to parking on the campus—was functional, but not in use while awaiting an automation project to be completed around the end of 2016. FDA officials provided no documentation to support why it chose not to implement vehicular access controls utilizing its campus security service's manpower while awaiting an automated system. As of October 2016, FDA officials stated that they were at an advanced stage of testing the automated system after which they would enter a 30-day review period prior to final implementation. However, FDA did not provide documentation describing its decisions for vehicular management, such as an implementation plan or a definitive time frame for completion.³⁸ The absence of these security features or any documented risk management decisions, such as an explanation for why FDA decided not to implement recommended security features, means that FDA has not fulfilled the requirements as laid out by the ISC.

³⁶Interagency Security Committee, *The Risk Management Process for Federal Facilities: An Interagency Security Committee Standard*, Appendix B: Countermeasures 2nd Edition (Washington, D.C.: January 2016).

³⁷In commenting on a draft of this report, FDA officials stated that until 2015 when the south east quadrant of the campus was completed establishing a vehicle security perimeter would not have been possible due to the high number of construction personnel and construction vehicles that needed to gain access to the site.

³⁸In commenting on a draft of this report FDA officials stated that final implementation is now scheduled for January 2017.

Furthermore, by not mitigating known risks associated with a high-risk facility, FDA may be putting the White Oak campus at risk.³⁹

Space management. FDA officials and staff reported that the agency has faced challenges in managing office space at the White Oak campus, in part, due to the growth in staff at FDA since the campus was planned in 2009, the delay in planned construction of two planned office buildings, and OMB's "Freeze the Footprint" initiative.⁴⁰ According to FDA officials, the need to accommodate more staff than was originally planned for the White Oak campus within the current footprint of the buildings has led FDA to take certain actions. For example, FDA has moved one unit that was initially relocated to White Oak off the campus, delayed the relocation of one FDA office—currently in leased nongovernment-owned space—to the White Oak campus, and expanded the use of its telework programs as a tool to mitigate space-management challenges.⁴¹ (See fig. 5.) In addition, FDA has implemented alternative office strategies, such as desk sharing, office sharing, and hoteling. In addition, FDA has installed office cubicles in some common spaces, such as building lobbies.

Each of these actions has had associated challenges, according to some FDA officials and staff with whom we spoke. For example, Office of Regulatory Affairs officials cited a number of challenges related to the fact that the office, which was twice scheduled to move to White Oak, remains largely in leased facilities. These challenges included missed opportunities for interaction between the majority of Office of Regulatory Affairs staff located away from White Oak and Office of Regulatory Affairs leadership located at White Oak, and office space and parking concerns for when Office of Regulatory Affairs staff not located at White Oak must travel there for meetings.

³⁹The FDA White Oak campus is designated a "high-risk facility" due to the size of the facility, the number of staff, and the nature of the laboratories on the campus.

⁴⁰Executive Office of the President, Office of Management and Budget, *Promoting Efficient Spending to Support Agency Operations*, Memorandum No. 12-12 (Washington, D.C.: May 11, 2012); OMB Memorandum No. 2013-02, Implementation of OMB Memorandum M-12-12 Section 3: *Freeze the Footprint* (Washington, D.C.: March 14, 2013); and OMB Memorandum No. 2015-01, Implementation of Memorandum M-12-12 Section 3: *Reduce the Footprint* (Washington D.C.: March 25, 2015).

⁴¹The 2009 White Oak master plan called for the offices of Center for Veterinary Medicine and the Office of Regulatory Affairs to be located on the White Oak campus by 2014. As of June 2016, more than 500 Office of Regulatory Affairs staff were still located in leased space in Rockville, Maryland.

In general, officials noted the added effort required for collaboration between Office of Regulatory Affairs staff located in three leased locations, as well as between staff in those locations and the staff located at White Oak. In addition, while some staff we spoke with stated that telework had improved their work-life balance, while allowing FDA to accommodate more people on site, FDA officials and staff we interviewed told us that collaboration required more effort as the number of staff teleworking has increased. Some FDA staff we interviewed reported that office sharing and expanded use of cubicles has been challenging for those staff who routinely handle proprietary information related to drug applications, or those who handle sensitive personnel related tasks.⁴² A union official representing FDA staff reported that decisions about which staff are assigned to single versus shared offices are based on various criteria, such as length of time at FDA, but are not based on the sensitivity of the work performed by staff.⁴³

⁴²For example, staff indicated that reviewing drug applications containing proprietary information can be challenging in an office that is shared with other individuals. Moreover, these staff said that supervisory staff who routinely give confidential feedback on personnel matters cannot do so in a shared office.

⁴³In commenting on a draft of this report, FDA officials noted that according to the memorandum of understanding between FDA and its employee union governing alternative officing, employees may be exempt based on the work being performed and the mission of the organization.

Figure 5: A Shared Office Configuration at the Food and Drug Administration's White Oak Campus



Source: GAO. | GAO-17-87

Transportation and parking. FDA officials and staff reported the agency faces challenges providing staff and visitors easy access to the White Oak campus, given its distance from area rail stations.⁴⁴ FDA offers several options to access the campus. For example, staff and visitors have the option of (a) commuting to the campus by car pools and van pools; (b) using FDA shuttles and public buses running between the campus and several area metro stations; and (c) parking their private cars in several parking garages, in temporary surface lots, or in a remote parking lot on the Federal Research Center adjacent to the campus. FDA runs a shuttle bus around the surface and remote parking lots to assist people in getting from their cars and from the transit stop at Building 1 to

⁴⁴According to officials, prior to the consolidation at White Oak, the majority of FDA's labs and offices were located in and around Rockville and Gaithersburg in the western part of Montgomery County in Maryland. These locations are serviced by several rail stations. Moreover, officials said many FDA staff lived in Rockville and Gaithersburg. Due to the configuration of existing rail networks, the commute for a majority of FDA staff living in Rockville and Gaithersburg to the White Oak campus in the eastern part of Montgomery County is significantly longer than it used to be prior to the consolidation.

various campus buildings. In addition, FDA offers staff and visitors the option of attendant-assisted parking in the parking garages and at the southeast parking lot, which increases the parking capacity of these locations.⁴⁵ FDA staff who attended our small group sessions expressed satisfaction with the variety of commuting options offered by FDA; however, they noted, for example, that the limited frequency of shuttles and buses to and from area metro stations reduces staff flexibility and can increase commute times.

According to FDA officials, the White Oak campus has a shortage of parking spaces for the campus population (staff, contractors, and visitors), which FDA has worked to mitigate through the use of attendant-assisted parking, temporary surface lots, and comingling of visitor and staff parking to maximize the efficiency of available parking.⁴⁶ (See fig. 6.) Two of the five parking garages planned in the 2009 master plan were not built, and would have provided 3,297 permanent parking spaces. Due to the construction of temporary surface parking lots, officials told us that the campus has reduced the deficit of parking spaces to 940 spaces, compared to the planned inventory of parking spaces of 6,926.⁴⁷

Moreover, some staff we spoke with were reluctant to use the remote parking lots, stating that due to their distance from the main campus buildings, either waiting for the shuttle or walking were time consuming and added significantly to their overall commute times. FDA staff we interviewed reported that commuting challenges and daily parking concerns affect the quality of work-life on the White Oak campus. For example, some staff we interviewed reported that they changed their work schedule so they arrive on campus as early in the morning as possible,

⁴⁵According to officials, the assisted parking services at the White Oak campus work as follows: When a parking garage or surface parking lot that has assisted parking services is full, attendants direct drivers to designated parking locations—for example, in the circulation aisles. Drivers park their cars in the designated locations, give their keys to the attendant and receive a claim ticket. Departing staff present their claim ticket to attendants who return the car key. Staff retrieve their cars and depart the parking garage.

⁴⁶According to officials, by not having dedicated parking for FDA staff and visitors, the White Oak campus is able to operate with fewer than the optimal number of parking spaces for the campus population.

⁴⁷According to FDA, there are a total of 5,986 parking spaces on the White Oak campus. This includes 3,224 spaces in parking garages, 2,698 in surface parking lots, and 64 in the remote parking lot. In addition, the assisted parking service adds an additional 590 parking spaces during peak hours of the day. With attendant assisted parking, the White Oak campus has a deficit of 350 planned parking spaces, relative to the master plan (940-590).

and before all the available parking spaces are gone. Moreover, several staff reported that they are generally reluctant to leave the campus during the middle of the day to attend meetings with other FDA units not located at White Oak, or to attend medical or personal appointments, because of concerns about parking when they return to campus.

Figure 6: Commuting and Parking Options at the Food and Drug Administration's (FDA) White Oak campus



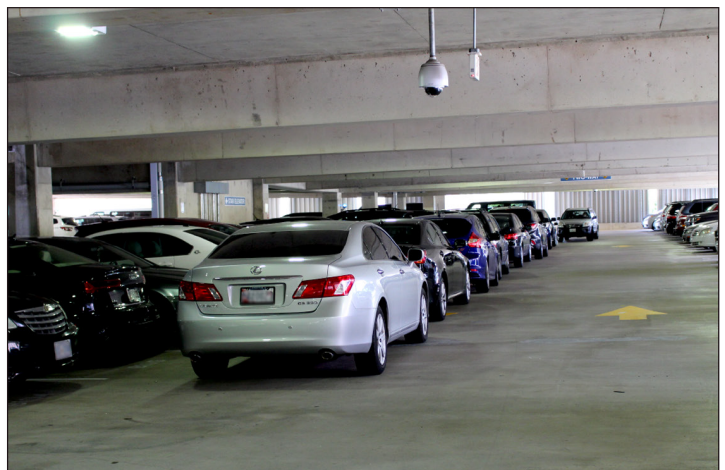
Surface parking lot



Washington Metropolitan Area Transit Authority buses



Parking garage



Attendant assisted parking

Source: GAO. | GAO-17-87

Distribution center. FDA officials reported the White Oak campus also faces challenges managing the delivery and distribution of packages, supplies, and other materials to staff and contractors. The master plan

included a distribution center that was meant to serve as the central point of arrival for deliveries to the White Oak campus.⁴⁸ According to FDA officials, the distribution center was not built because the cost to complete all the elements of the master plan exceeded the available funding. In the absence of the distribution center, distribution activities are conducted in ad-hoc spaces within the service tunnel system that runs under the campus buildings.⁴⁹ (See fig. 7.) According to officials, the service tunnel system was not designed for this purpose and is overcrowded, thereby potentially creating a safety and security hazard. Officials reported that the construction of the distribution center is a high priority for FDA as it plans for the future of the White Oak campus.

Figure 7: Existing Basement Tunnel at White Oak Campus Used as Distribution Point for Supplies Due to Lack of Distribution Center



Source: GAO. | GAO-17-87

⁴⁸According to FDA officials, the distribution center was planned to provide space for centralized logistics management for receiving, materials management and distribution, equipment storage, and collection of outgoing waste and recycled materials.

⁴⁹According to FDA officials, the distribution center is programmed to include specialty areas for an expanded mail room; additional security screening equipment for incoming materials; storage of maintenance supplies; storage of mobile conveyance support, including forklifts and carts; and information technology equipment receiving and preliminary configuration.

FDA and GSA Planning for the Future of White Oak Has Not Fully Incorporated Leading Capital and Strategic Facilities Planning Practices

FDA and GSA have taken steps to accommodate additional FDA staff on the White Oak campus, and FDA has advocated for the completion of some unfinished elements of the master plan concurrent with a master plan update. However, White Oak facilities planning efforts have not fully incorporated key elements of leading capital and strategic facilities planning practices, thereby limiting FDA's assurance that its facilities strategy is furthering its mission and that information necessary for understanding facility needs is incorporated into existing and proposed planning efforts.

FDA and GSA Have Begun Planning for the Future of the White Oak Consolidation Project

In September 2015, FDA published an update to a 5-year facilities plan that incorporated a discussion of the future of the White Oak consolidation project along with other facilities priorities agency-wide (referred to as the existing plan).⁵⁰ In addition, FDA is working in consultation with GSA on two proposed facilities planning efforts, (1) a housing strategy and migration plan and (2) a new Federal Research Center master plan (referred to as the proposed planning efforts). (See table 2.)

⁵⁰Department of Health and Human Services, Food and Drug Administration, Office of Facilities, Engineering, and Mission Support Services, *2017 Five-year Strategic Facilities Plan: Addressing FDA Facilities Needs for 2016-2020*. (Silver Spring, Md.: Sept. 30, 2015).

Table 2: The Food and Drug Administration (FDA) and General Services Administration's (GSA) Current and Proposed Facility Planning Efforts for White Oak

Document Name	Purpose	Responsible Agency
2017 Five-year Strategic Facilities Plan (existing)	An annually updated agency-wide 5-year facilities planning document, most recently published in September 2015, providing information on FDA's needs across its entire portfolio of facilities, both within the national capital area and field locations, and addressing issues related to lab condition, ongoing maintenance needs, further consolidation of FDA staff, and space challenges.	Internally developed by FDA
FDA Housing Strategy and Migration Plan (proposed)	A proposed planning effort designed to evaluate FDA's headquarters housing need for accommodating current staff and projected growth, and develop a migration plan for geographically consolidating FDA functions on the Federal Research Center, including the White Oak campus, at nearby federal locations that house FDA headquarters staff, and/or at nearby leased buildings.	Contractor, under the coordination of GSA and FDA
FDA Headquarters: The Federal Research Center Master Plan Project (proposed)	A proposed planning effort designed to update the most recent White Oak Master Plan by incorporating the evaluations from the above housing strategy. The master plan update intends to provide GSA and FDA with a structured framework and alternatives for the future use and development of the Federal Research Center, including the White Oak campus, with an emphasis on accommodating projected staff growth. ^a	Contractor, under the coordination of GSA and FDA

Source: FDA and GSA planning documents and associated scopes of work. | GAO-17-87

^aIn addition, FDA and GSA have proposed an additional master planning effort intended to assess potential development options and environmental impact of housing between 500 and 2,000 additional staff at its other FDA headquarters facilities located at the Muirkirk Road Complex in Laurel, Maryland.

In its existing plan, FDA created a 5-year forecast of the agency's facility needs, including a broad look at FDA's facility portfolio across the national capital area and its field locations, while focusing on laboratory revitalization, improving federally owned assets, and providing adequate space in the national capital region and the field to accommodate anticipated growth and meet the agency's mission.⁵¹ According to FDA, this effort led FDA to determine its need to increase the number of staff located on (or near) the White Oak campus by 5,900 by fiscal year 2020.⁵²

⁵¹According to FDA, this staff growth is driven by staffing increases related to user fees, among other reasons, such as the increasing health care needs of an aging U.S. population and additional rules for tobacco oversight.

⁵²Of this projected growth, 3,000 are current FDA staff assigned to locations in and around the national capital area that the agency plans to move to the White Oak campus, or nearby. The remaining 2,900 reflects anticipated staff increases through ongoing or projected agency hiring efforts. According to FDA officials, FDA is currently validating these growth estimates through ongoing planning processes, which will consider user-fee agreements that are being re-negotiated for fiscal year 2018.

In its existing plan, FDA highlighted a number of issues specifically related to the future development of the White Oak campus:

- FDA stressed that the full intent of the consolidation at White Oak—to centralize labs, office buildings, and support in order to speed operational excellence and ensure a scientifically stronger FDA—has not been fully met due to funding limitations. Specifically, FDA stated that there is a need for the three buildings (one office building, a distribution center, and a global communications center) and associated infrastructure (including parking garages) that were included in the master plan, but not built. According to GSA officials, a broader and validated examination of FDA’s needs in the national capital area, such as is called for in the proposed planning, is needed before GSA is likely to request funding for a new capital project at White Oak.
- FDA stated that some centers located at White Oak will be able to continue to absorb growth within their existing space footprint. FDA stressed its efforts to improve its space utilization (from 222 usable square feet per person to 171 usable square feet per person in fiscal year 2015) in line with federal guidance to freeze and reduce the footprint. However, FDA also stated that the White Oak campus is nearing its full capacity and that in some cases building systems and site infrastructure were becoming over-taxed.
- FDA stated that it has lacked reliable and up-to-date data on office space usage, including information on the number of employees and contractors, and to what office space each is assigned. FDA’s central data source has been incomplete (in its existing plan, FDA estimated its facilities management system as 85 percent accurate, prior to its ongoing validation process) and calls to each center to validate data have been time consuming and have not always resulted in accurate information. In its existing plan, FDA described a number of recommended efforts to improve the accuracy of these data, such as coordination of space planning efforts between FDA centers and its Office of Operations, and further leveraging of centralized data from FDA’s position management and workforce planning activities.

FDA’s proposed planning efforts are intended to recommend a strategy for geographically consolidating current and projected FDA employees (as determined through FDA’s strategic facilities planning process) within current federally owned and leased facility assets, including White Oak, and leasing options for office space located nearby, and to define how

best to develop the Federal Research Center and White Oak campus in alignment with this strategy.⁵³ According to GSA officials, procurement for these proposed planning efforts commenced in September 2016, with an anticipated final delivery in early 2019.

FDA's Existing and Proposed Planning Efforts Do Not Fully Incorporate Leading Capital and Strategic Facilities Planning Practices

FDA's planning for the future of the White Oak campus incorporates some elements of leading capital and strategic facilities planning, but lacks a fully developed linkage to its strategic priorities and information needed to clearly demonstrate the gap between existing facilities and agency needs. According to the International Facility Management Association (IFMA), OMB, and our prior work, leading capital and strategic facility planning practices emphasize an agency-wide approach to planning by

1. setting a strategic linkage between agency facility goals and strategic priorities,
2. conducting an assessment to demonstrate the gap between all current assets and the current and future agency needs, and
3. evaluating alternative approaches to close the gap.⁵⁴

⁵³The scope of work for the FDA Housing Strategy and Migration Plan (June 2016) calls for an assessment of all FDA locations in the national capital area, with particular attention to White Oak, the Muirkirk Road Complex in Laurel, Maryland, and the Wiley Building in College Park, Maryland. *The FDA Headquarters: The Federal Research Center Master Plan Project* (June 2016 scope of work) will update the master plan by incorporating assessments of existing site and building conditions on the Federal Research Center; appropriate types, locations, and orientations of future uses; cultural buildings, cultural landscapes, and archaeology; open space and natural resources; transportation modes and infrastructure; site access and security; utility infrastructure; environmental contamination/hazardous materials; storm water management; and climate change considerations.

⁵⁴IFMA is an international professional association that advances facilities management through professional credentialing of facility managers, research, and training. According to IFMA, a strategic facilities plan is "defined as a two-to-five year facilities plan encompassing an entire portfolio of owned and/or leased space that sets strategic facility goals based on the organization's strategic (business) objectives." We have considered IFMA guidance along with OMB guidance in our prior facilities work, including for campus-like facilities. See, for example, [GAO-15-410](#). See also OMB, Capital Programming Guide, Supplement to Office of Management and Budget Circular A-11: *Planning, Budgeting, and Acquisition of Capital Assets* (July 2016), and [GAO/AIMD-99-32](#). In addition, in [GAO-11-197](#) we established a framework for evaluating the implementation of the concepts that underlie the capital planning best practices.

These efforts help agencies contextualize strategic facility planning within the agency's broader strategic capital planning vision.

Strategic linkage. FDA incorporated broad references to the agency's mission and vision within its existing plan and proposed planning efforts. For example, FDA's existing plan states the agency's role in protecting and advancing public health and safety, and its responsibility to combat emerging threats. It also references the strategic role FDA facilities play in "providing the appropriate infrastructure and scientific capabilities to keep FDA functioning optimally and able to carry out its mission, while also responding to public health emergencies," and describes the goals of the consolidation at White Oak.

These broad references generally tie the existing plan to FDA's mission needs. However, within the existing plan, FDA does not create explicit strategic linkages between the agency's recommended facility strategy, particularly in sections related to the White Oak campus, and the agency's broader strategic goals and objectives. Leading capital and strategic facilities planning practices emphasize the importance of an agency's ability to align facility planning decisions with agency strategic goals and objectives. For example, OMB's guide states that capital assets should be planned for, acquired, and managed based on their ability to contribute to accomplishing program outputs and outcomes as described in an agency's strategic plan. In our prior work, we discussed the Department of Veterans Affairs' explicit incorporation of the agency's specific strategic goals as weighted criteria when prioritizing potential strategic facilities projects.⁵⁵ According to FDA officials, such linkages were implicit to the agency's strategic facilities planning process. Moreover, FDA officials stated that FDA linked its facilities efforts and its strategic goals in its fiscal year 2017 budget justification—which, for example, states that facilities and rental investments ensure FDA staff have functioning offices and labs across the country to execute its food safety and medical product safety mission. These statements place FDA's facilities program in the context of its mission. However, in relying on such general linkage, FDA's existing plan does not explicitly establish a linkage that would allow it to plan for capital assets based on their ability to contribute to accomplishing program outputs and outcomes described

⁵⁵For example, one of the criteria by which the Department of Veterans Affairs prioritized potential capital projects included "Departmental Alignment," which includes the Secretary's goals for improving management and performance and the department's strategic goals. See [GAO-11-197](#).

in FDA's strategic priorities. For example, when describing approaches to managing projected staff growth within the national capital area, FDA did not demonstrate how recommended actions would help accomplish specific FDA strategic objectives. Using more explicit linkage, FDA could have demonstrated how planning solutions designed to accommodate additional staff in consolidated locations, including White Oak, were prioritized or recommended based on an ability to accomplish specific FDA strategic objectives, such as enhancing productivity and capabilities or improving the overall operation and effectiveness of FDA.

Moreover, without explicit strategic linkages between the existing plan's strategic recommendations and agency strategic goals and objectives, FDA has limited assurance that decisions based on these facilities planning efforts—such as how best to accommodate and consolidate growth in the national capital area by modifying existing space, procuring additional leased space, or further developing the White Oak campus—are appropriately prioritized within the context of FDA's strategic goals and objectives. The lack of defined strategic linkage may thereby limit the usefulness of the plan in considering how to best support the agency's mission in future facilities efforts.

Further, the proposed planning efforts call for incorporating FDA's mission and several mission-related objectives, but also do not explicitly define a linkage to FDA's strategic priorities, particularly in defining how the proposed planning outputs will further FDA's mission and meet its facility needs.⁵⁶ For example, the scope of work for the housing strategy and migration plan (as described in table 2) requests that the contractor hired to develop this plan review opportunities for FDA to increase co-location and consolidation within the White Oak campus in order to improve mission effectiveness, create a unified FDA organization, increase organizational efficiency, size the real estate portfolio appropriately to fit the mission of FDA, and reduce real estate occupancy costs. In addition, the background materials supporting proposed planning efforts include agency mission, goals, and strategic objectives. However, deliverables for these efforts are not required to incorporate explicit linkages between recommended approaches and FDA's strategic priorities, thereby limiting

⁵⁶According to GSA officials, the agency incorporates a number of standards, including those established by GSA, executive orders, and other best practices, to inform its master planning processes.

FDA's assurance as to how its facilities strategy would further the agency's mission. For example, the scope of work for the housing strategy and migration plan does not call for an incorporation of FDA's strategic priorities, such as its ability to recruit, develop, retain, and strategically manage a world-class workforce, as key factors in developing and assessing alternatives for accommodating future staff growth.

Needs assessment, gap identification, and alternatives evaluation. FDA's existing plan and proposed planning efforts for the future of the White Oak campus incorporate some elements of leading practices related to needs assessment, gap identification, and alternatives evaluation, but limitations in FDA's data collection may make it challenging to ensure that needed information is incorporated into these new planning efforts.

IFMA recommends that strategic facility plans incorporate input from all departments within an organization. Consistent with this, FDA's existing plan incorporated information from separate planning meetings with key officials within each office and center to present data and planning summaries, and elicit feedback and needs. These meetings allowed FDA to capture center-specific needs and incorporate planning factors that may impact each center's space management activities in different ways.

Moreover, according to IFMA and our prior work, strategic facilities and capital planning efforts should include an assessment of all real property assets and their conditions (federally owned and leased), in order to identify the performance gap between current and needed capabilities. Information and feedback on asset performance, condition, cost of programs, and operations are critical to making informed facilities decisions.⁵⁷ While FDA's existing plan does not incorporate a condition assessment of current facilities at White Oak—which FDA officials emphasized is the responsibility of GSA—the proposed planning efforts call for such an assessment. This assessment, if implemented as called for, may help FDA and GSA better analyze the gap between existing conditions and agency facility needs. However, documentation of the proposed planning efforts was not clear about the extent to which this gap will be addressed during the planning process.

⁵⁷ [GAO/AIMD-99-32](#).

In addition, leading capital and strategic facilities planning practices emphasize the importance of evaluating the full range of alternatives to meet the gap between current assets and identified needs. In line with leading practices, FDA's proposed planning efforts for the future White Oak campus include an evaluation (including cost analysis) of several housing strategies to support FDA's space management needs in the national capital area. FDA and GSA have proposed consideration of on-site construction at White Oak and other federally owned facilities, leasing in nearby facilities, and renovations of existing facilities, or other alternatives across its entire portfolio within the national capital area. According to proposals, the efforts will inform the development of four alternative strategies, including a preferred alternative, to consider for potential future development, reflecting distinct conceptual designs and life-cycle cost estimations.

While FDA's incorporation of these leading practices into its existing plan and proposed planning efforts is a good first step, limitations in FDA's data collection may make it challenging to ensure that needed information is incorporated in alignment with leading practices, which emphasize the importance of accurate information to inform capital decision-making. In addition, standards for internal controls recommend that agencies gather and assess data to help manage day-to-day operations and plan for the future.⁵⁸

FDA has limited data on the following:

- Daily campus population: FDA has collected limited data on the number of FDA staff, contractors, and visitors that come onto the White Oak campus each day, in part, according to FDA officials, due to challenges keeping up-to-date information on staff and contractors. Following our request for this information, FDA conducted an analysis of unique badge swipes during a 5-week period—from February to March 2016. FDA officials later told us that this information was useful for their planning efforts. While the analysis FDA performed at our request offers insight into campus usage, it does not necessarily reflect a seasonally representative timeframe, nor does the underlying data easily integrate with information needed to monitor other ongoing

⁵⁸GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

facility stressors, such as daily parking trends, electrical or heating, venting, and air conditioning (HVAC) overload, or conference room availability. Without robust data on the trends in daily, weekly, and monthly numbers of FDA staff, contractors, and visitors on the campus, FDA will face challenges managing its transportation infrastructure—especially parking—and planning for the future of the White oak campus. In commenting on a draft report, FDA officials stated that they had periodically collected data on campus population in the past. As mentioned, FDA’s existing 5-year facilities plan notes challenges related to validating staffing numbers and office space information for the White Oak campus, and describes a number of recommended improvement efforts, although the success of these efforts is not yet clear. Also, proposed planning efforts call for the development of a tool that includes facility-level graphics showing staff occupancy for all FDA locations, as well as “quantitative and qualitative aspects of the existing space situation.” The extent to which this proposed tool will solve some of FDA’s data challenges is not yet clear.

- Office usage: Data on how telework and shared offices, and other space management strategies highlighted in the existing facilities plan affected office usage were incomplete and, according to officials, have not yet been collected for future planning efforts. Moreover, FDA had done little to assess the benefits or challenges related to increased telework.⁵⁹
- Parking availability: FDA has limited data on the number of parking spaces actually used each day, making it difficult to assess the validity of general concerns about parking availability and to plan for the future. FDA provided data on the inventory of current parking spaces on campus, and an analysis of the number of tickets collected by the attendant-assisted parking service over several months, which FDA believes provides a partial view of on campus parking trends. According to FDA officials, this limited data could not be correlated to evaluate how many of each category of staff, contractors, and visitors park on campus each day. For example, because the card access drive-on gates regulating access to the White Oak campus and its parking facilities were not operational, FDA officials told us that full information on daily parking metrics for staff and visitors—data that could be used to pinpoint infrastructure strains from overcrowding on

⁵⁹FDA is not alone in its lack of assessment of the effects of increased telework. We recently reported that many federal agencies are facing challenges providing data measuring the costs and benefits of increased telework. See [GAO-16-551](#).

the campus and better assess the agency's facility needs—were unavailable. Proposed planning efforts call for an analysis that evaluates parking capacity as part of the development of a transportation management plan.

- Building system and site infrastructure capacity: FDA lacks quality information on the effects of increased staff growth on building systems and site infrastructure at White Oak, such as HVAC overload, meeting space availability, and cafeteria congestion. FDA cited concerns in its existing plan that the building systems were being taxed due to the number of staff at White Oak, but FDA officials told us the concerns were, for the most part, based on anecdotal evidence of complaints from employees about building conditions rather than a formal evaluation.
- Consolidation benefits: Our prior work has shown that consolidation initiatives based on a clearly presented business case, grounded in accurate and reliable data, can provide a data-driven rationale for why an agency is undertaking a particular initiative and show stakeholders that a range of alternatives has been considered.⁶⁰ While FDA has some data on the benefits of consolidation, such as reduced spending on outside conference centers, other information has not been systematically collected for planning purposes. For example, FDA lacks systematically collected data (such as from a survey) to support claims of enhanced scientific collaboration, or improved recruitment and retention, and had not undertaken staff surveys of views on the consolidation. FDA officials stated that these benefits, and others associated with the consolidation, are difficult to quantify, and that an emphasis on completing the consolidation and managing the campus's day-to-day needs superseded an analysis of benefits. While we recognize that such benefits can be difficult to quantify, we have cited circumstances in which agencies produced such information. For example, in our 2016 report on federal telework benefits and costs,

⁶⁰See GAO, *Streamlining Government: Questions to Consider When Evaluating Proposals to Consolidate Physical Infrastructure and Management Functions*, [GAO-12-542](#) (Washington, D.C.: May 23, 2012). In this report, we identified key questions that agencies should consider when evaluating whether to consolidate physical infrastructure and management functions and illustrated the questions with agency consolidation examples. To develop these leading practices, we reviewed the consolidation literature; selected seven consolidation initiatives at the federal level in various stages of completion and one recommended consolidation; reviewed documentation and interviewed agency officials with responsibility for the initiatives; and interviewed public-management and government-reform experts with consolidation experience.

we found that some agencies had gathered supporting data for some cited benefits, such as by conducting a survey.⁶¹ There may also be additional ways FDA could collect information to support cited benefits, such as by tracking achievements made through collaboration, or benefits from the program described earlier that was implemented by FDA's Office of the Chief Scientist to share costly, new scientific equipment. Without more systematically collected and analyzed information on these and other benefits, it is unclear how FDA will accurately assess consolidation alternatives.

The scopes of work for FDA's proposed planning efforts state generally that data should be collected in areas where adequate data do not exist, are unverifiable, or insufficient. However, proposed planning deliverables do not specify a detailed strategy for collecting and analyzing key information related to daily operational activities, and ongoing benefits and challenges at White Oak. As a result of these current data limitations, FDA's facilities planning efforts offer limited assurance that recommendations developed for the future of the White Oak campus will accurately represent the full scope of facility needs and account for all current and future performance gaps.

Conclusions

FDA headquarters staff and operations consolidation at the White Oak campus between 2003 and 2014 resulted in greater collaboration and efficiency and improved laboratory facilities, according to FDA officials. However, FDA officials and staff also reported challenges associated with managing space needs on the White Oak campus, in particular given the partial completion of the facilities identified in the master plan. Specifically, due to space and logistics challenges, FDA has not implemented a vehicle-separation system controlling visitor access on the White Oak campus that is required by its high-risk designation, nor has it documented its rationale for this decision based on an assessment of risk, as required. Complying with these requirements will help ensure that the agency has minimized security risks at the campus.

FDA's planning for the future of the White Oak campus incorporates elements of leading capital and strategic facilities planning practices, but lacks some elements designed to ensure its plans are strategically sound. Without an explicit linkage between FDA's facilities planning efforts and specified strategic objectives, it will be difficult for FDA to support and

⁶¹See [GAO-16-551](#).

implement its vision for the future of White Oak and its other facilities, or to evaluate the potential effect of different proposed alternatives on FDA's mission. Additionally, without key information documenting daily operational activities—such as the number of staff on campus and the number of cars needing parking spaces—and ongoing benefits and challenges related to the White Oak campus, it will be difficult for FDA to validate its needs assessment and gap analysis, or to strategically consider the alternatives that are to be developed in its upcoming planning efforts. Furthermore, in considering whether and how to bring more staff to the White Oak campus, FDA must determine how to prioritize support facilities designed for the current campus, but not built, including the parking garages and distribution center. The indication in proposed planning efforts that developing more robust data will be part of this effort is a good start. However, it is not possible to determine from these early documents the extent to which these new efforts will fully incorporate a strategy for the collection and analysis of needed key information related to daily operational activities and ongoing benefits and challenges at White Oak. While the last capital funding for the White Oak campus was provided in fiscal year 2012, FDA has projected continued staff increases in the headquarters area and within the centers located at White Oak. Therefore, FDA's proposed planning efforts provide an opportunity for FDA and GSA to develop a robust analysis, either from existing data at FDA or through new efforts, such as the tool described in the agencies' proposed planning efforts, that will allow them to make a strong business case for the best approach for the future of the White Oak campus.

Recommendations for Executive Action

As FDA moves forward with its proposed planning efforts, we recommend that the Commissioner of FDA, in consultation with the Administrator of GSA, take the following steps in order to ensure that the agency is adequately protecting the White Oak campus as a designated high-risk facility and strategically planning for the White Oak campus's future:

1. Implement vehicular access control measures on the White Oak campus to meet the requirements of the high-risk facility level designation assigned in the 2014 risk assessment report, or fully document the rationale for any deviations from these requirements.
2. Further incorporate leading strategic facilities planning practices into FDA's proposed planning efforts by ensuring that FDA establish strategic linkage between its strategic priorities and its facilities plans.

-
3. Document the key information related to daily operational activities and ongoing benefits and challenges that are needed to inform FDA's proposed planning efforts in the areas of needs assessment, gap identification, and alternatives analysis, and incorporate into proposed planning efforts a detailed strategy for collecting and analyzing this information.

Agency Comments

We provided a draft copy of this report to the Department of Health and Human Services (HHS) and GSA for their review and comment. Both agencies provided written comments, which are reprinted in appendix III and appendix IV. HHS concurred with our recommendations, and stated that the recommendation to implement vehicular access control measures to separate FDA staff and visitors is in the process of being implemented. In addition, HHS noted several ongoing planning efforts at the White Oak campus related to elements of our recommendations. GSA reviewed the draft and agreed with the overall nature of the findings. GSA and HHS also provided technical comments that were incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 1 week from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Administrator of the General Services Administration, and other interested parties. In addition, the report will be available at no charge on GAO's website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact Elizabeth H. Curda at (202) 512-7114 or CurdaE@gao.gov or David J. Wise at (202) 512-2834 or WiseD@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix V.



Elizabeth H. Curda
Acting Director, Health Care



David J. Wise
Director, Physical Infrastructure Issues

Appendix I: Authority and Funding for Development of the Food and Drug Administration's White Oak Campus

Table 3: General Services Administration Authority and Funding for Development of the Food and Drug Administration's White Oak Campus, Fiscal Year (FY) 1992 to 2012

Authority	Funding (\$1,000)
Public Law 102-141 (FY 1992) ^a	\$57,669
Public Law 103-123 (FY 1994)	73,921
Funds Reprogrammed (FY 1994)	6,000
Public Law 103-329 (FY 1995)	45,000
Public Law 104-19 (FY 1995) Rescission	(228,000)
Funds Reprogrammed (FY 1995)	(5,000)
Public Law 104-52 (FY 1996)	55,000
Public Law 106-58 (FY 2000)	35,000
Public Law 106-554 (FY 2001)	92,179
Public Law 107-67 (FY 2002)	19,060
Public Law 108-7 (FY 2003)	37,600
Public Law 108-199 (FY 2004)	42,000
Public Law 108-447 (FY 2005)	88,710
Public Law 109-115 (FY 2006)	127,600
Public Law 110-5 (FY 2007)	178,526
Public Law 110-161 (FY 2008)	57,749
Public Law 111-8 (FY 2009)	163,530
Public Law 111-117 (FY 2010)	137,871
Public Law 112-10 (FY 2011)	43,043
Public Law 112-74 (FY 2012)	10,000
Total	\$1,037,458

Source: GAO analysis of General Services Administration data. | GAO-17-87

Notes:

^aA total of \$200 million was authorized in 1992, of which \$57.669 million was for the White Oak campus, and the balance went to other Food and Drug Administration projects in Prince George's County, Maryland, and technical studies.

Appendix II: Funding Sources for the Food and Drug Administration's White Oak Consolidation

Table 4: Food and Drug Administration's White Oak Campus Funding Sources, Fiscal Year 2002 to 2016

Fiscal Year	Project	Appropriated Funds (\$1,000)	Proceeds from User Fees (\$1,000)	Total Funds (\$1,000)
2002	Life Sciences Laboratory I (Building 64)	\$0	\$4,000	\$4,000
2004	Office Buildings 21/22 Infrastructure	2,361	3,770	6,131
2005	Office Buildings 21/22 Fit-out and Relocation and Central Shared Use (CSU) I Infrastructure	17,849	11,330	29,179
2006	Engineering and Physics Laboratory Building 62, Data Center Phase I and CSU I Fit out	21,753	5,033	26,786
2007	Building 51, Data Center Phase II, Building I Infrastructure, Fit out	25,557	10,105	35,662
2008	Building 66, Data Center Phase II, Building I Infrastructure, Fit out	38,536	4,173	42,709
2009	Building 31/32, CSU Phase II, Data Center Phase IV Building 66	38,779	2,660	41,439
2010	Building 31/32, CUS Phase II, Data Center Phase V, Buildings 52/72, Building 10 Vivarium, Building 71 Phase I	38,536	2,960	41,496
2011	Building 71 Phase I, Building 75 Phase I, Southeast Quad Infrastructure	38,459	3,415	41,874
2012	Building 71 Phase II, Buildings 52/72 Phase II	34,926	3,415	38,341
2013	Building 71 Phase III, Building 75 Phase II	46,721	3,475	50,196
2014	Buildings 10 Vivarium, 71, 75 and 52/72, 75 Commissioning and Occupancy	47,601	3,559	51,160
2015	SE Quad Changes, Decommissioning, Campus Support Infrastructure, Campus Utility Infrastructure improvements, Program Management Support	22,762	3,643	26,405
2016	Update to Master Plan, Campus support/utility infrastructure improvements, Program Management Support	7,983	4,302	12,285
Total		\$381,823	\$65,840	\$447,663

Source: GAO analysis of Food and Drug Administration data. | GAO-17-87

Appendix III: Comments from the General Services Administration



The Administrator

November 17, 2016

The Honorable Gene L. Dodaro
Comptroller General
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Dodaro:

The U.S. General Services Administration (GSA) appreciates the opportunity to review and comment on the U.S. Government Accountability Office (GAO) draft report entitled, *FDA Facilities: Planning Efforts for White Oak Campus Should Further Incorporate Leading Practices to Address Ongoing Challenges* (GAO-17-87). GAO recommends that the Commissioner of the U.S. Food and Drug Administration (FDA), in consultation with the Administrator of GSA, take the following steps to ensure that the agency is adequately protecting the White Oak campus as a designated high-risk facility and strategically planning for the White Oak campus's future:

- a. Implement vehicular access control measures on the White Oak campus to meet the requirements of the high-risk level designation assigned in the 2014 risk assessment report, or fully document the rationale for any deviations from these requirements.
- b. Further, incorporate leading strategic facilities planning practices into FDA's proposed planning efforts by ensuring that FDA establishes strategic linkage between its strategic priorities and its facilities plans.
- c. Document the key information related to daily operational activities and ongoing benefits and challenges that are needed to inform FDA's proposed planning efforts in the areas of needs assessment, gap identification, and alternative analysis, and incorporate into proposed planning efforts a detailed strategy for collecting and analyzing this information.

We have reviewed this report in depth, and agree with the overall nature of the findings. Enclosed are technical comments that respond to GAO's recommendations.

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Washington, DC 20405-0002
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If you have any questions or concerns, please contact me at (202) 501-0800, or Ms. Lisa Austin, Associate Administrator, Office of Congressional and Intergovernmental Affairs, at (202) 501-0563.

Sincerely,



Denise Turner Roth
Administrator

Enclosure

cc: Ms. Elizabeth H. Curda, Acting Director, Health Care, GAO
Mr. Chris Currie, Director, Homeland Security and Justice, GAO
Mr. David Wise, Director, Physical Infrastructure Issues, GAO

Appendix IV: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 23 2016

Elizabeth Curda
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Curda:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*FDA Facilities: Planning Efforts for White Oak Campus Should Further Incorporate Leading Practices to Address Ongoing Challenges*" (GAO-17-87).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in cursive script, reading "Jim R. Esquea", is positioned above the printed name and title.

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FDA FACILITIES: PLANNING EFFORTS FOR WHITE OAK CAMPUS SHOULD FURTHER INCORPORATE LEADING PRACTICES TO ADDRESS ONGOING CHALLENGES (GAO-17-87)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

The Food and Drug Administration appreciates GAO's review in examining the Agency's efforts to consolidate its workforce at the White Oak Campus in Silver Spring, Maryland. Collaboration, cooperation and cohesiveness are hallmarks of the interdependent nature of FDA's components. FDA's workforce was highly fragmented, with dozens of facilities scattered around the Washington DC area. The construction of modern infrastructure and facilities at the White Oak Campus was essential for FDA's growth in size and scope as well as for enhancing the quality of life of employees.

Having employees within close proximity of one another supports the integration of FDA science, which is critical to the Agency's ability to maintain its pre-eminence as a science-based and science-led agency. The facilities on this campus provide critical scientific capacity, with scientists working in modern laboratories equipped with the latest technologies and tools.

GAO Recommendation 1

GAO recommends that FDA, in consultation with GSA, take the following steps in order to ensure that the Agency is adequately protecting the White Oak Campus as a designated high-risk facility and strategically planning for the White Oak Campus' future:

Implement vehicular access control measures on the White Oak Campus to meet the requirements of the high-risk facility designation assigned in the 2014 risk assessment report, or fully document the rationale for any deviation from these requirements.

HHS Response

FDA concurs. Because of the White Oak Campus' size in acreage and occupancy, FDA and GSA officials continue to oversee its safety and security. FDA concurs with GAO's recommendations and has already begun to implement campus access controls.

FDA's Office of Safety, Security, and Crisis Management, together with the Office of Facilities Engineering and Mission Support Services, are in the process of activating campus-wide vehicular access control measures. The controls will be implemented in three phases to minimize impact on the occupants. The first phase began on November 14, 2016, and full implementation is anticipated by the end of January 2017. On November 3, 2016, vehicular access control measures and timelines were communicated to FDA's metropolitan area staff.

Phase 1

Phase 1, initiated on November 14, 2016, will involve the redirection of all Campus visitors, and vehicles without an FDA-badged employee on board, to the North Surface Visitor Parking Lot. Visitors will no longer be able to park in employee parking areas located inside the security posts.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FDA FACILITIES: PLANNING EFFORTS FOR WHITE OAK CAMPUS SHOULD FURTHER INCORPORATE LEADING PRACTICES TO ADDRESS ONGOING CHALLENGES (GAO-17-87)

Phase 2

Phase 2 will begin in mid-November and will test the Fast Pass and security gate traffic lights. In Phase 2, traffic signals will be tested for the Fast Pass lanes and will indicate whether a vehicle's Fast Pass is working.

Phase 3

Phase 3 is planned to begin in mid-December, at which time security gate arms will be activated. Only vehicles with active Fast Pass or employees and contractors/visitors with a valid PIV badge will be allowed to cross the campus security perimeter and park in the designated employee parking areas. We anticipate full implementation by the end of January 2017.

GAO Recommendation 2

Further incorporate leading strategic facilities planning practices into FDA's proposed planning efforts by ensuring that FDA establishes strategic linkages between its strategic and facilities planning.

HHS Response

FDA concurs. In addition, to incorporating leading strategic facilities planning practices into FDA's proposed planning efforts, FDA updates its strategic priorities document every four years. This document describes FDA's work to address complex, multifaceted, and evolving public health issues. FDA last published its strategic priorities document in September 2014, entitled, *FDA Strategic Priorities 2014-2018* (<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM416602.pdf>).

The five cross-cutting strategic priorities identified in this document include

1. Regulatory Science,
2. Globalization,
3. Safety and Quality,
4. Smart Regulation, and
5. Stewardship.

As FDA develops its FY2018 Strategic Facilities Plan and collaborates with GSA to produce the proposed FDA Housing Strategy and Migration Plan and update the Federal Research Center Master Plan, the Agency will ensure that linkages are established in these documents to these five cross-cutting strategic priorities, as applicable. For example, regulatory science is the science of developing new tools, standards, and approaches to assess the safety, effectiveness, quality, toxicity, public health impact, or performance of FDA regulated products. FDA's Strategic Facilities Plan identifies laboratory revitalization as a key component of the plan. Modern, flexible laboratories are needed to advance regulatory science, and this linkage will be made in the FY2018 Strategic Facilities Plan. In addition, the consolidation of FDA's product centers at White Oak creates opportunities for scientific synergy that can lead to advancements in regulatory science. Consolidation of the Office of Regulatory Affairs on or near the White Oak Campus will produce additional opportunities for scientific collaboration that can be linked to both advanced regulatory science and improved planning to monitor the global economy (i.e., globalization).

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FDA FACILITIES: PLANNING EFFORTS FOR WHITE OAK CAMPUS SHOULD FURTHER INCORPORATE LEADING PRACTICES TO ADDRESS ONGOING CHALLENGES (GAO-17-87)

GAO Recommendation 3

Document the key information related to daily operational activities and ongoing benefits and challenges that are needed to inform FDA's proposed planning efforts in the areas of needs assessment, gap identification, and alternatives analysis, and incorporate into proposed planning efforts a detailed strategy for collecting and analyzing information.

HHS Response

FDA concurs. To inform FDA's proposed headquarters consolidation planning efforts, FDA will incorporate data regarding employees and visitors arriving on its White Oak Campus including the number of cars. FDA will determine the appropriate frequency at which these data will be collected and analyzed in order to adequately and effectively support planning efforts.

In addition, FDA understands that GSA will also seek to incorporate GAO's recommendations into the Master Planning process by contracting for Building Evaluation Reports (BER) to provide additional building information to supplement the Master Planning process as funding allows.

FDA will also work with GSA to ensure that the FDA Housing Strategy and Migration Plan will include alternatives analyses. The analyses will include a review of the most effective linkages to FDA's Strategic Priorities.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Elizabeth H. Curda (202) 512-7114 or CurdaE@gao.gov
David J. Wise (202) 512-2834 or WiseD@gao.gov

Staff Acknowledgments

In addition to the contact named above, Alwynne Wilbur (Assistant Director), N. Rotimi Adebajo (Analyst in Charge), George Depaoli, Will Garrard, Daniel Friel, Camilo Flores, and Drew Long made key contributions to this report.

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